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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,985	08/14/2001	James K. Mainquist	P1013US10	3858
29490 7590 07/02/2007 GENOMICS INSTITUTE OF THE NOVARTIS RESEARCH FOUNDATION 10675 JOHN JAY HOPKINS DRIVE, SUITE E225 SAN DIEGO, CA 92121-1127			EXAMINER SODERQUIST, ARLEN	
			ART UNIT 1743	PAPER NUMBER
			NOTIFICATION DATE 07/02/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPLegal@gnf.org
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Office Action Summary

Application No.

09/929,985

Applicant(s)

MAINQUIST ET AL.

Examiner

Arlen Soderquist

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17-24, 27-35 and 37-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 17-24, 27-35 and 37-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on April 30, 2007 has been entered.

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the curved surface of claim 7, the pin of claim 8 and the additional component(s) for performing assays or reactions in microtiter plates of claims 29-34 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. Claims 1-15, 17-24, 27-35 and 37-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the claims, the structure of the microtiter plate is not well defined. Thus there is some question as to what constitutes an inner and an outer wall. Thus for examining purposes the term outer wall will be treated by examiner as a wall that defines the perimeter of the microtiter plate and any structure connecting it to the walls and/or

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structure which defines the wells of the microtiter plate. An inner wall for examining purposes is being treated by examiner as any wall or structure that defines the wells of the microtiter plate. Thus, relative to the claims that require alignment members, examiner will treat any wall or structure that defines the well section of the microtiter plate as an inner wall and a structure that protrudes from the support and contacts this wall or structure will be treated as anticipatory of that feature of the claims. Relative to the software claim (claim 42), examiner notes that the placing step of claim 39 is written in a manner that it included manually placing the microtiter plate on the support. Thus this step is not being treated as limiting on the software claim along with the position that the microtiter plate is placed relative to the alignment members. Instant paragraph [00042] shows that the point of contact with the microtiter plate is preferably the inner wall but that it is not exclusively required to align the microtiter plate. Thus is also the description that is being used as the basis for the way examiner is treating the claims.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1-4, 12-15 and 17-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Bevirt (US 6,063,579). In the patent Bevirt teaches an alignment mechanism to precisely position a work surface to facilitate the transfer of materials in an automated manner. In column 1, Bevirt teaches that a microtiter plate or other piece of laboratory equipment that is subject to multiple rounds of heating and cooling during a series of manipulations may become nonuniform in the flatness of its working surface causing the depth of individual wells to vary and resulting

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in problems with automated material transfer from the plate. The invention overcomes the described problem during material transfer processes by providing a method for flattening or elongating the work surface in order to precisely align the work surface in relationship with a dispenser. Figure 1 shows the positioning means (24,26) including structure on two perpendicular axes (see column 3, lines 1-14). In figures 4-5 the functioning of the device is taught. As illustrated in figure 4, a plate, such as a 384-well microtiter plate (50), is placed on a mold (52). The figure shows the positioning of the microtiter plate prior to applying pressure. The microtiter plate is shown elevated from the bottom surface (54) of the mold and supported by the top portion (56) of an elastomeric seal (58). An internal structure (60, alignment member in contact with an inner wall of the plate) is used to correctly position the microtiter plate with respect to the structure prior and during the application of a vacuum. The figure also shows a vacuum channel (62) leading from a vacuum port to individual vacuum outlets. Figure 5 illustrates how the plate is deformed to flatten the work surface of the assay plate once pressure is applied. The microtiter plate (70) has a plurality of wells (72), each having a well bottom (74), which may contact the bottom surface (76) of the mold. An internal structure (78, alignment member in contact with an inner wall of the plate) keeps the microtiter plate centrally positioned with respect to the rest of the mold and any material dispenser positioned above the mold structure. Once pressure is applied, the elastomeric seal (80) is sufficiently flexible to allow for vertical or horizontal motion of the outer rim (82) of the plate when the plate is compressed against the substantially planar upper surface (84) of the mold. The position of the center region (86) is maintained by the internal structure. Typically, as a consequence of the movement of the plate, the shape of the elastomeric seal has changed. Since the outer wall of the microtiter plate is being defined by examiner to include wall structure that connects the wall that defines the perimeter to the wall structure that defines the well section and the inner wall is defined as the wall or structure that makes up the well section of the microtiter plate, Bevirt is anticipatory of the claims. Additionally instant paragraphs [00052]-[00054] show that the point of contact of the lip with the microtiter plate is a bottom surface of the microtiter plate.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. Claims 1-15, 17-24, 27-35 and 37-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burton (WO 99/04228) or Modlin (US 6,071,748) in view of Cathcart (US 5,443,791), Markin (US 5,417,922) and Bevirt as explained above. The published application and the Modlin patent have equivalent disclosures. Since both have equivalent disclosures the patent will be described. The anticipatory disclosure in the published application is shown in figures 40-43 and described on pages 46-51. In the patent Modlin describes a high-throughput light detection instrument. Figure 24 shows a general structure in which the light detection instrument is a part. Column 2 lines 56-62 discusses what is typical in current automated high-throughput analyzers including assay analyzers, liquid handling systems, robotics, computers for data management, reagents and assay kits, and microplates for automation of sample dispensing to data collection. In figures 22(a-c) and 23 Modlin teaches a transporter assembly used in the light detection device of the patent. Figures 22a-b show a stage for supporting a composition for analysis by the analyzer in the form of a transporter (600). The transporter includes a transporter body (602) and substantially parallel first and second transporter flanges (604a,b) that extend outward from the transporter body. First and second transporter flanges terminate in first and second transporter extensions (606a,b) that turn in toward one another without contacting one another. The transporter body, flanges, and extensions lie substantially in a plane and define a transporter cavity (608) that is larger than any sample containers that the transporter is intended to support. The shape of this cavity, rectangular, is chosen to accommodate the shape of the preferred sample containers, such as microplates. In the analyzer, long sides of the rectangular

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sample container are positioned against the flanges. Transporter shelves (610) along portions of the body, the flanges, and the extensions form a structure that supports the bottom of the sample container. Other support mechanisms, such as **pins or pegs**, also could be employed instead of or in addition to shelves. The transporter also includes an automatic sample container positioning mechanism (620) for precisely and reproducibly positioning sample containers within the cavity along Y and X axes with positioning arms (622a,b) that contact the sample container to control its Y and X position, respectively. The Y-axis positioning arm (622a) lies substantially within a channel (624) in the body and includes a rod (626a) having the bent shape shown. A first end (628a) of the rod terminates near the cavity with a bumper tab (630a,632) for engaging a sample container. A second end (634a) of the rod terminates away from the cavity in an actuator tab (636a) for controlling movement of the arm. An Y-axis biasing spring (642a) is present. X-axis positioning arm (622b) also lies substantially within the channel (624) in the body and is similar to the Y-axis positioning arm, except that the first end segment (628b) terminates in a lever tab (630b) in the X-axis positioning arm rather than a bumper. The X-axis positioning arm is connected via the lever tab to an X-axis positioning lever (654) that lies along the transporter flange (604b). The X-axis positioning lever includes two functional lever projections (656,658) and is pivotally mounted about a lever pivot axis (659) on the transporter near the intersection of the body and the flange (604b). A first lever projection (656) is substantially perpendicular to the flange (604b) and abuts the lever tab on the X-axis positioning arm for actuating the positioning lever. A second lever projection (658) also is substantially perpendicular to the flange (604b) and includes an edge (660) for contacting a sample container. In use the transporter occupies a loading position substantially outside a housing for a person, robot, or mechanical stacker to place a sample container into the cavity so that the bottom of the sample container rests on the transporter shelves. Under the action of both positioning arms, the sample container is precisely and reproducibly positioned (registered) against a reference corner (672) within the cavity. The biasing springs (642a,b) can be chosen to have different strengths, so that the X-Y positioning action is performed less or more forcefully. As long as the microplate is placed in any position on the lower guide shelves, it can be adjusted into place by the automatic microplate positioning mechanism. A sensor (not shown) detects the presence of the sample container. The transporter can also eject the sample containers. Figure 23 shows a

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perspective view of the transporter mounted on base platform (700) with drive mechanisms for moving the transporter between loading and examination positions. The drive mechanism is provided multiple mechanisms for moving the transporter. Since the microtiter plate is not positively recited as an element of the structure, where it is touched by the alignment member(s) has no patentable moment relative to the positively recited structure. The Burton application and Modlin patent do not teach specifics regarding the structure for liquid handling systems, robotics and reagent, assay kit and microplate storage.

In the patent Cathcart teaches an automated Molecular biology laboratory. In the device a liquid-handling instrument has a worksurface with registration for modular stations to support containers of liquid, pipette apparatus with a pipette tip coupled to a sensing circuit, a robotic translation system for moving the pipette tip, and a control system with an iconic user interface for programming and editing. A gauge block registered on the worksurface provides for calibration using the sensing tip, and register cavities on the worksurface provide for modular stations. There is a wash station for the pipette tip on the worksurface. An automated laboratory based on the liquid-handling system has heating and cooling and a sealable incubation station as well as a magnetic separation station. Methods are disclosed using the apparatus to convey droplets of liquid, to aspirate with minimum tip contamination, to mix liquids in containers, and to validate the worksurface. Procedures in chemistry, particularly in biochemistry, present generally more difficult problems for automation than many other kinds of processes and procedures. One reason is that there is often a very long sequence of steps in a biochemical procedure, such as gene detection and sequencing DNA. Another is that an automatic system needs to be very versatile, because different kinds of starting materials and different analytical purposes require different steps, different order of steps and the use of different kinds of chemical reagents. A third is that sample quantity is, for various reasons, quite limited, and only very small volumes, often on the order of microliters, must be used. What is needed is automatic robotic apparatus for doing liquid transfers with very small quantities of liquids, and in a manner that avoids carryover and evaporation. Such an instrument needs to be modular in nature so that container stations may be interchanged, with modular stations for holding containers so that such operations as sample preparation and cleaning may be done off-line. Methods for operation of such apparatus are needed allowing a relatively large number of samples to be processed at a

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time, with samples and reagents placed in a close array to preserve space. The robotic actions need to be rapid to minimize overall processing time and extremely accurate to be able to access many small sites. Such an apparatus needs to be integrated with a control system that allows an operator to easily and quickly set up procedures with different variables, different step sequences, and different samples and reagents. Also needed is laboratory apparatus based on such a liquid handling system to incorporate further techniques, such as temperature control and a separation station, to be able to fully automate specific chemistry protocols such as for gene detection and DNA sample purification. The general form of the apparatus is shown in figure 1 and for performing DNA sequencing the automated laboratory has a closeable, heated, clamped-lid thermal cycling station (21), an actively cooled enzyme storage station (23), a wash station (25), a reagent storage position (27) for storing and presenting frequently used reagents, a DNA sample stage (28), a wash buffer storage (30), and two magnetic particle wash stations (26,29) for manipulating paramagnetic particles in suspension in liquid mixtures. Also shown is a gauge block (24) for use in calibrating the robotic drives for the apparatus. The various stations are arranged on a worksurface (22). In the preferred embodiment the stations on the worksurface are registered in cavities machined into the worksurface maintaining close tolerance dimensions from cavity to cavity and to the position of the gauge block, so modular stations may be interchanged while maintaining information about the position of containers relative to the worksurface and the gaugeblock.

In the patent Markin teaches a specimen carrier for transporting conventional specimen tubes throughout an automatic laboratory conveyance system includes a generally rectilinear carrier body with a forward face having an identification zone delimited thereon. An identification code is marked in the identification zone so as to permit mechanical sensing and identification of the carrier on a conveyor system. A plurality of holes of various diameters and depths are provided in the top surface of the carrier to receive conventional specimen tubes of various types with the top ends of the specimen tubes located at a predetermined height above the top surface of the carrier. A specimen carrier (10) may be temporarily stored on storage racks (70), as shown in figure 6. Each storage rack includes a base plate (72) with a plurality of locator pins (74) projecting upwardly from the upper surface of the base plate. Locator pins are arranged in sets of pairs that are longitudinally spaced apart so as to correspond with a pair of

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apertures (62,64, see figure 3) on each specimen carrier. Pin pairs are spaced apart laterally a distance such that specimen carriers are laterally spaced apart to permit the specimen carrier to be grasped by the jaws (76) of a robot arm (78).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the various components of Cathcart, Markin and Bevirt into the Burton or Modlin analyzers because of the ability to carry out complex procedures such as the high-throughput procedures of Burton or Modlin in a minimal amount of time as taught by Cathcart. It additionally would have been obvious to one of ordinary skill in the art at the time the invention was made to have placed the alignment members of Burton or Modlin so that they would contact an inner wall of the microtiter plate as shown by Bevirt because of the positioning capabilities of placing alignment members as taught by Bevirt.

8. Applicant's arguments filed April 23, 2007 have been fully considered but they are not persuasive. Relative to the objections of the drawings, it is noted that there are several rules relating to the drawings. The section that applicant cited, 37 CFR 1.81, is related to when applicant is required to provide drawings. It does not give the requirements for the content of the drawings. 37 CFR 1.83 is the rule that deals with the content of the drawings. Paragraph (a) requires that "the drawing in a nonprovisional application **must show every feature of the invention specified in the claims**" (emphasis added). Thus the requirement for drawing content is not what one of skill in the art needs to understand the invention or what one of ordinary skill in the art envisions based on the description provided, but every feature of the invention that is specified in the claims. While features that are old can be represented in block form where appropriate, the features specified in the claims are required to be shown in the patent rules. For these reasons, the drawings do not meet the content requirement in that they do not show the structure of claims 7, 29 and 32 and the claims that depend therefrom. Furthermore, applicant is required to respond to these objections in a specified manner (by providing substitute or replacement figures) to avoid abandonment.

Relative the anticipation rejection by Bevirt, examiner has found a clarity issue with the claims relative to what constitutes an inner wall and an outer wall. In considering how the two terms should be properly handled, examiner decided that since applicant had not defined the microtiter plate structure, a definition of an inner wall should include any wall or structure that

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defines the well section of the microtiter plate. Thus when the alignment structure of Bevirt contacts a wall of the wells as shown in the figures, this is within the scope of in contact with an inner wall. Likewise, the outer wall is being treated by examiner to include the wall defining the microtiter plate perimeter and any connecting structure that connects that wall to the inner wall or well section of the microtiter plate. By this definition Bevirt still anticipates the listed claims. Examiner also points out that the same structure can be used to contact an inner wall or an outer wall depending on the placement of the microtiter plate and the presence of an inner wall in the microtiter plate. The instant specification at paragraph [00042] also teaches that contacting an inner wall is preferred but does not limit the alignment contact to the inner wall. Additionally, it is noted that the perimeter surface is not well defined in the instant specification. Paragraphs 52-54 (pages 14-15) clearly teach that it is a bottom surface of the plate that interacts with the lip of the vacuum retaining device. In the Bevirt reference, it is also clearly a bottom surface of the microtiter plate that contacts the lip. Since the Bevirt reference meets what is disclosed in the example of the instant specification, Bevirt anticipates the requirement/capability that a perimeter surface of the microtiter plate contact the lip surface when the microtiter plate is in the desired position.

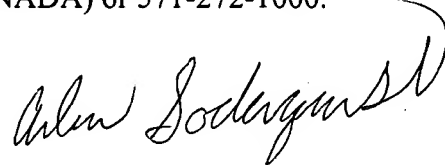
Relative to the Burton or Modlin references, examiner has changed all claims to an obviousness rejection and the positioning of the alignment means of Burton or Modlin has been modified based on the definition of inner and outer walls noted above and the alignment disclosure of Bevirt. Thus the rejection is a new ground of rejection and applicant's arguments are moot.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (571) 272-1265. The examiner can normally be reached on Monday-Thursday and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'Arlen Soderquist', with a stylized flourish at the end.

Arlen Soderquist
Primary Examiner
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